

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

CALIFORNIA MEDICAL PRODUCTS, INC., :
Plaintiff :
v. : C.A. No. 91-0542L
EMERGENCY MEDICAL PRODUCTS, INC., :
Defendant :

MEMORANDUM AND ORDER

RONALD R. LAGUEUX, United States District Judge.

This matter is presently before the Court on plaintiff's motion for preliminary injunction pursuant to 35 U.S.C. § 283 (1988). Plaintiff California Medical Products, Inc. ("CalMed") holds the patent for a cervical extrication collar marketed as "STIFNECK™." CalMed seeks to preliminarily enjoin defendant Emergency Medical Products, Inc. ("EMPI") from manufacturing and selling its extrication collar, known as the "Ultimate Collar," on the ground that EMPI's collar infringes CalMed's U.S. Patent No. RE32,219 (the '219 patent). EMPI denies any infringement and moves for summary judgment pursuant to Fed. R. Civ. P. 56(b).

I. BACKGROUND

CalMed manufactures and sells cervical extrication collars used by paramedics and emergency medical technicians to immobilize the head and neck of emergency victims during transportation, preliminary examination, and treatment. The collars consist of two pieces cut from flat sheet plastic: a neck band and a chin rest. The asymmetrical neck band encircles the patient's neck and closes on the side with velcro. The chin

rest is permanently attached to the neck band at two locations: one end of the chin rest is fastened to the side of the neck band, and the center of the chin rest is fastened to a tab extending from the upper edge of the neck band. The other end of the chin rest remains unattached until ready for use, enabling the collar to be stored flat. Prior to application, the free end of the chin rest is snapped in place, and the collar forms a cylindrical shape that can be readily slipped around the neck of a prone patient and secured. The collars are made of radiolucent plastic that allows X-rays to be taken while the collar is worn. Geoffrey Garth, CalMed's president and the inventor of STIFNECKTM, received the patent for his unique collar design in 1983. CalMed now occupies about two-thirds of the extrication collar market.

When EMPI sought to enter the extrication collar field, its president, William Burns, examined all those collars already on the market to find the best design. After surveying the field, EMPI began producing cervical extrication collars almost exactly like CalMed's STIFNECKTM. When CalMed became aware of this, CalMed requested that EMPI cease and desist its infringing activity. EMPI denied any infringement. Consequently, CalMed filed this action.

In October 1991 EMPI redesigned its Ultimate Collar by widening the tab that extends from the upper edge of the neck band and deepening the gaps on either side of the tab. EMPI claims that this new design does not infringe CalMed's patent

because these modifications distinguish the Ultimate Collar from the '219 patent claims, especially the claims stating that the chin rest is "supported along its entire length" by the upper edge of the neck band. Recently, EMPI has produced the same design in foam, marketed as the "EXL Disposable Collar." These two models (Pl.'s Ex. 5, the hard collar; Pl.'s Ex. 10, the foam collar) are the subjects of plaintiff's motion for preliminary injunction and defendant's motion for summary judgment.¹ After conducting a full evidentiary hearing, the Court took the matter under advisement. The motions are now in order for decision.

II. CALMED'S MOTION FOR PRELIMINARY INJUNCTION

In deciding a motion for preliminary injunction, this Court must consider the following factors:

- 1) CalMed's reasonable likelihood of success on the merits;
- 2) the potential for irreparable injury to CalMed if relief is denied;
- 3) the balance of hardships tipping in CalMed's favor; and
- 4) the impact of the injunction on the public interest.

Hybritech Inc. v. Abbott Lab., 849 F.2d 1446, 1451 (Fed. Cir. 1988); see also Narragansett Indian Tribe v. Guilbert, 934 F.2d 4, 5 (1st Cir. 1991).

¹ On June 5, 1992, the parties agreed in court to a consent judgment that EMPI would be permanently enjoined from making, using, or selling any collars of its previous design as exemplified by Plaintiff's Exhibit 13.

A. Reasonable Likelihood of Success on the Merits

CalMed must first establish its reasonable likelihood of success on the issue of patent validity. Hybritech, 849 F.2d at 1451. A patent is born valid, and its validity endures until a challenger has "so carried his burden as to have persuaded the decisionmaker that the patent can no longer be accepted as valid." Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1534 (Fed. Cir. 1983); see 35 U.S.C. § 282 (1988). In order to meet its burden of persuasion, EMPI would have to demonstrate at trial, by clear and convincing evidence, that the '219 patent is invalid. Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861, 872 (Fed. Cir. 1985). On this motion for preliminary injunction CalMed must show that EMPI would fail to prove such invalidity. H.H. Robertson, Co. v. United Steel Deck, Inc., 820 F.2d 384, 387-88 (Fed. Cir. 1987).

At present, EMPI has asserted no basis for invalidity. In response to CalMed's motion for preliminary injunction, EMPI fails to discuss the issue of invalidity, focusing only on the issue of infringement. Furthermore, EMPI assumes the validity of the '219 patent for the purposes of its summary judgment motion.

On three prior occasions, CalMed sought to enjoin infringement of the '219 patent. Each of these actions resulted in a consent judgment in which the infringing party acknowledged the validity of the '219 patent and agreed to a permanent injunction. While these consent judgments do not constitute prior adjudications of the '219 patent's validity, they

nevertheless indicate the patent's validity because of the infringing parties' acquiescence. Id. at 388. For these reasons the Court finds it reasonably likely that EMPI would fail to prove the '219 patent invalid at trial.

Next, the Court must consider CalMed's reasonable likelihood of success on the issue of infringement. Hybritech, 849 F.2d at 1451. The grant of a preliminary injunction does not require the moving party to prove beyond all question that there has been infringement, nor to prove that no evidence exists to support the accused infringer's arguments. H.H. Robertson, 820 F.2d at 390. Instead, CalMed must show a reasonable likelihood that it will meet its burden at trial by proving either literal infringement or infringement by equivalents. Id.

1. Literal Infringement

A finding of literal infringement requires the Court to conclude that the accused device embodies every element of the patent claim. Builders Concrete, Inc. v. Bremerton Concrete Prods. Co., 757 F.2d 255, 257 (Fed. Cir. 1985). This requires a two-step analysis: the Court first determines the scope of the patent claims; then the Court determines whether the properly constructed claims encompass the accused structure. Hybritech, 849 F.2d at 1455. The first step is a legal question with underlying factual issues, while the second is a factual question. Id.

The patent claims at issue in this case are independent claims 1 and 4 of the '219 patent. Claim 1 provides:

1. A cervical collar formed entirely of:
 - (a) an elongated neck encircling band formed entirely of stiff, flexible plastic sheet material having front, side and opposite side portions;
 - (b) a chin support brace, also formed entirely of stiff flexible plastic sheet material having a generally C-shape including fastening means located on each end of said brace;
 - (c) said chin support brace fastening means being engageable with cooperative attachment means located at least on opposite side portions of said neck encircling band such that when said band is formed into said collar at least one of said fastening means is allowed to align with a respective attachment means thus bowing said brace thereby enabling said brace to obtain an upwardly inclined, conically convex chin rest supported along its' entire length by the upper edge of the front portion of said band and projecting forwardly therefrom;
 - (d) collar retention means carried at each end of said band and mutually cooperative to retain said band in its collar configuration.

Claim 4 similarly provides:

4. A cervical collar formed of a stiff, flexible plastic sheet band having an asymmetrical configuration comprising:
 - (a) an elongated neck encircling band formed of stiff, flexible sheet material having front, side and back portions with said back portion integral with one of said side portions whereby said band is joined together to form said collar at one side thereof;
 - (b) a chin support brace, also formed entirely of stiff flexible plastic sheet material having a generally C-shape including fastening means located on each end of said brace;
 - (c) said chin support brace fastening means being engageable with cooperative attachment means located at least on opposite sides of said neck encircling band such that when said band is formed into said collar at least one of said fastening means is allowed to align with a respective

attachment means thus bowing said brace thereby enabling said brace to obtain an upwardly inclined, conically convex chin rest supported along its' entire length by the upper edge of the front portion of said band and projecting forwardly therefrom; and

- (d) collar retention means, one each carried at the side end and at the back end of said band and mutually cooperative to retain said band in its collar configuration.

The remaining eight claims are dependent on either claim 1 or claim 4. The parties have narrowed the issue to focus on subpart (c) of claims 1 and 4, which states in pertinent part that the chin rest is "supported along its entire length by the upper edge of the front portion" of the neck band.

The language used to define a patent claim limits the scope of that claim. Coleco Indus., Inc. v. United States Int'l Trade Comm'n, 573 F.2d 1247, 1253 (C.C.P.A. 1978); see 35 U.S.C. § 112 (1988). EMPI argues that "supported along its entire length" means that the chin rest must be in constant contact with the upper edge of the neck band along its entire length. The Ultimate Collar does not exhibit such constant contact, EMPI argues, because the central tab distances the chin rest from the upper edge, with gaps on either side. EMPI asserts, therefore, that its collars do not meet the scope of the claims and do not literally infringe CalMed's patent.

The Court finds, however, that EMPI's proposed construction of the claims is not in accord with the actual language because "supported along its entire length" does not mandate constant contact. "Support" does not mean the same thing as "constant

contact." Therefore, an item made out of an inherently stiff material, such as the hard plastic from which these collars are made, is "supported along its entire length" without constant contact, and the presence of gaps does not alter that support. Thus, constant contact is not called for by the patent claims.

Construed in this manner, the '219 patent clearly encompasses the accused device. The chin rest in the '219 patent is supported by the upper edge of the neck band, which is precisely where EMPI's central tab is located. While EMPI would have the Court believe that the tab itself provides the support, the facts suggest something different. Unlike prior collar designs that supported their chin rests with an inflexible metal bar attached to the front face of the collar, EMPI's tab extends from the upper edge of the neck band in one continuous piece. When the collar is worn, the tab flexes away from its static position to form a right angle with the neck band. The point of support between the chin rest and the neck band then becomes the line at the base of the tab, where the tab extends out from the upper edge. Thus, the tab is merely an extension of the upper edge of the neck band, and the point of support is located where the upper edge would be if the tab were not present. See Mannesmann Demag Corp. v. Engineered Metal Prods. Co., 793 F.2d 1279, 1282-83 (Fed. Cir. 1986) (presence of elements not described by patent claim irrelevant if all claimed elements present). This conclusion is supported by two in-court demonstrations.

During the hearing Garth removed the fastener between the chin rest and the tab to show that, on a subject, the chin rest remained in the same position as if the fastener were in place. Later in the hearing, CalMed's attorney cut the tab at its base. Again, the chin rest did not drop down. Without the downward force of a patient's head, however, the chin rest pivoted upward on its side rivets. Thus, Garth added the central tab to the original design to facilitate application of the collar on a patient. Once the collar is in place, the tab serves no essential function.

This Court finds, therefore, that the language "supported along its entire length by the upper edge of the front portion" of the neck band literally encompasses the design embodied by EMPI's collar.

2. Doctrine of Equivalents

Even if CalMed had not established a reasonable likelihood of success on the issue of literal infringement, the Court concludes that CalMed has established a reasonable likelihood of success pursuant to the doctrine of equivalents.

[T]he test of equivalency extends beyond what is literally stated in a patentee's specification to be equivalent and encompasses any element which one of ordinary skill in the art would perceive as interchangeable with the claimed element. If a patentee were bound by the literal language of his specification and claims, the purpose of the doctrine of equivalents, to give relief against the copier who merely makes insubstantial substitutions in a claimed invention, would be frustrated. Thus, the proposition that the claims, taken in view of the specification, measure the metes and bounds of the invention has been realistically tempered by the judicially-formulated doctrine of equivalents.

Thomas & Betts Corp. v. Litton Sys., Inc., 720 F.2d 1572, 1579 (Fed. Cir. 1983). Simply stated, the Court determines whether the accused device performs substantially the same function in substantially the same way to obtain the same result. Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608 (1950). This factual determination is made with reference to the patent claims, the prior art, and the circumstances of the case. Id. at 609. Furthermore, the doctrine of equivalents is applied to the claimed invention as a whole, not to a particular aspect of it. Hughes Aircraft Co. v. United States, 717 F.2d 1351, 1364 (Fed. Cir. 1983). Applying the doctrine of equivalents in this case results in the following analysis.

First, both the claimed device and the accused device perform substantially the same function. Each prevents further injury to an accident victim's spine by immobilizing the head and neck during the initial transportation, examination, and treatment.

Second, both devices use substantially the same means to immobilize a patient. Each prevents the patient's head from dropping down to the chest by resting the head on the chin rest. The underside of the chin rest engages the encircling neck band, which blocks the chin rest's descent. On the claimed device, this point of contact is defined as the upper edge of the neck band, while on the accused device it is the line where the base of the tab meets the upper edge, as discussed above. This distinction alone is insufficient to support a finding that the

two devices do not perform in substantially the same way. Were the Court to require an obvious and exact equivalent, literal infringement would have been proved, thereby rendering the doctrine of equivalents superfluous. Id.

Third, both devices achieve the same result. Each collar successfully restrains the patient's head and neck from forward, rotational, and lateral movement. Accordingly, the Court finds that EMPI's Ultimate Collar performs substantially the same function in substantially the same way to achieve the same result as the claimed device.

There is, however, an important limitation upon the doctrine of equivalents known as prosecution history or file wrapper estoppel. During prosecution of the patent, an inventor may amend a claim, or argue for a certain construction of the claims, in order to differentiate the claimed device from the prior art. The inventor is then estopped from recapturing the surrendered subject matter of the original claim by invoking the doctrine of equivalents in an infringement action. Charles Greiner & Co. v. Mari-Med Mfg., Inc., 754 F. Supp. 951, 955 (D.R.I. 1991), aff'd, 1992 U.S. App. LEXIS 7942, 22 U.S.P.Q.2d 1526 (Fed. Cir. 1992). The Court must consider not only the amendment itself, but also the reasons for the amendment. Mannesmann, 793 F.2d at 1284-85.

Amendment of claims is a common practice in prosecution of patent applications. No reason or warrant exists for limiting application of the doctrine of equivalents to those comparatively few claims allowed exactly as originally filed and never amended. Amendments may be of different types and may serve different functions. Depending on the nature and purpose of an amendment, it may have a limiting effect

within a spectrum ranging from great to small to zero. The effect may or may not be fatal to application of a range of equivalents broad enough to encompass a particular accused product. It is not fatal to application of the doctrine itself.

Hughes Aircraft, 717 F.2d at 1363. Thus, while CalMed may be limited by the scope of its amended claims, it may yet be entitled to some range of equivalents. See Mannesmann, 793 F.2d at 1284.

The claims of the '219 patent were initially rejected by the Patent and Trademark Office ("PTO") for nonobviousness and anticipation by the prior art. In response to these objections, Garth amended the claims to narrow the scope of those found impermissible. The manner in which he amended them, however, does not preclude CalMed from raising the doctrine of equivalents in this action.

Garth amended subpart (c) of claims 1 and 4 to state that the collar included a "conically convex chin rest supported along its entire length by the upper edge of the front portion of said band and projecting forwardly therefrom." EMPI claims that its collar does not meet the range of equivalents bounded by CalMed's amended claims. The Court does not accept this argument.

Whether prior art restricts the range of equivalents of what is literally claimed can be a difficult question to answer. To simplify analysis and bring the issue onto familiar turf, it may be helpful to conceptualize the limitation on the scope of equivalents by visualizing a hypothetical patent claim, sufficient in scope to literally cover the accused product. The pertinent question then becomes whether that hypothetical claim could have been allowed by the PTO over the prior art. . . . If the hypothetical claim could have been allowed, then prior art is not a bar to infringement under the doctrine of equivalents.

Wilson Sporting Goods Co. v. David Geoffrey & Assocs., 904 F.2d 677, 684 (Fed. Cir.), cert. denied, 111 S. Ct. 537 (1990).

CalMed suggests two possible hypothetical claims that would meet this test.

The first hypothetical claim omits "along its entire length" to rewrite subpart (c) of claims 1 and 4 as follows: a "conically convex chin rest supported [] by the upper edge of the front portion of said band and projecting forwardly therefrom." This does not encompass the prior art because none of those designs used the upper edge of the neck band to support the chin rest. EMPI's device, however, relies upon the upper edge of the neck band, from where the tab extends, to support its chin rest. Therefore, this hypothetical claim meets the test.

A second hypothetical claim rewrites the same language to state that the chin rest is "supported [substantially] along its entire length by the upper edge." This claim, too, meets the test because it distinguishes the prior art that did not use the upper edge for support, but encompasses EMPI's device, which uses the upper edge to substantially support the entire chin rest.

In filing his claim amendments, Garth explained the distinctions between the '219 patent claims and those of the prior art. The reason for these distinctions was to differentiate the '219 patent from those prior art devices that used structures other than the upper edge of the neck band to support the chin rest. Garth also distinguished the prior art on the following grounds: those earlier designs were three-

dimensional and could not be stored flat; they were designed symmetrically with the closure in back; and they could not be worn during X-rays because of their metal components.

For these reasons the Court finds that CalMed has not attempted to resurrect any of the subject matter surrendered during prosecution of the '219 patent. Clearly, neither the amendments nor the distinctions drawn between the '219 patent and the prior art narrow the scope of the '219 claims sufficiently to exclude EMPI's Ultimate Collar from the range of equivalents. Therefore, prosecution history estoppel will not preclude CalMed from raising the issue of infringement by equivalents. Accordingly, CalMed has shown a reasonable likelihood of success on the merits of this issue.

B. Irreparable Injury

CalMed must also show that it is likely to suffer irreparable injury if the preliminary injunction is not granted. Such immediate, irreparable harm may be presumed from a strong showing of patent validity and infringement, as CalMed has made here. H.H. Robertson, 820 F.2d at 390. This presumption is buttressed by CalMed's occupation of two-thirds of the extrication collar market. While the presumption may be rebutted, EMPI has failed to argue that CalMed will suffer no irreparable harm. Id.

The essential value of a patent lies in the right it confers upon a patent holder to exclude others from infringing the invention. Smith Int'l, Inc. v. Hughes Tool Co., 718 F.2d 1573,

1581 (Fed. Cir.), cert. denied, 464 U.S. 996 (1983). This exclusionary right demonstrates the inability of money damages to make a plaintiff whole.

The patent statute provides injunctive relief to preserve the legal interests of the parties against future infringement which may have market effects never fully compensable in money. "If monetary relief were the sole relief afforded by the patent statute then injunctions would be unnecessary and infringers could become compulsory licensees for as long as the litigation lasts."

Hybritech, 849 F.2d at 1457 (citing Atlas Powder Co. v. Ireco Chems., 773 F.2d 1230, 1233 (Fed. Cir. 1985)). For these reasons the Court finds that CalMed would suffer irreparable injury if the preliminary injunction were not granted.

C. Balance of Hardships

The third consideration in deciding a motion for preliminary injunction is to balance the harm that will result to the moving party if the injunction is denied against the harm that will result to the other side if the injunction is granted. In this case, the balance of hardships weighs in favor of granting the preliminary injunction.

CalMed has occupied a significant portion of the cervical collar field since it introduced STIFNECKTM in the early 1980s. Denial of the motion for injunctive relief, therefore, would cause considerable harm to CalMed's reputation and threaten its market position. On the other hand, issuance of the injunction would force EMPI to remove only its Ultimate Collar from the marketplace until the Court could determine that there was no infringement. Because CalMed has shown a reasonable likelihood

of success, however, it is not clear that the Court would make such a determination. Accordingly, the Court finds that the potential harm to CalMed outweighs the potential harm to EMPI.

D. Public Interest

Finally, the Court must consider the impact of the injunction on the public interest. A preliminary injunction would remove EMPI's Ultimate Collar from the marketplace, thereby depriving the public of one source of extrication collars. EMPI, however, occupies a small share of the market, while CalMed occupies two-thirds of the market and could probably fill the gap left by EMPI's exclusion. While there is a public interest in product availability, it is unlikely that the public would suffer from a shortage of extrication collars if the injunction were granted. See Hybritech, 849 F.2d at 1458.

More importantly, the public interest weighs heavily in favor of granting a preliminary injunction where a reasonable likelihood of success on the merits has been shown. There is a strong public policy in favor of protecting valid patents, which is furthered by a grant of injunctive relief. H.H. Robertson, 820 F.2d at 391. Accordingly, the Court finds that issuance of the injunction would not harm the public interest.

E. Summary

For all of the above reasons it is clear that CalMed is entitled to a preliminary injunction regarding EMPI's hard plastic Ultimate Collar (Pl.'s Ex. 5).

As for EMPI's foam version of the Ultimate Collar (Pl.'s Ex. 10), the Court concludes that CalMed has not shown a reasonable likelihood of success on the merits. It is not clear that foam comes within the claims of the '219 patent, which specify "stiff, flexible plastic sheet material." It would be inadvisable for the Court to determine at this time whether the foam collar infringes upon CalMed's patent claims without more extensive development of the facts. Accordingly, the motion for preliminary injunction is denied as to the foam collar.

III. EMPI'S MOTION FOR SUMMARY JUDGMENT

Pursuant to Rule 56(b), EMPI has moved for summary judgment on both the hard plastic and foam versions of the Ultimate Collar. The standard for summary judgment is whether, taking the evidence in the light most favorable to the nonmoving party, there is no genuine issue as to any material facts pertaining to the issue of infringement. Palumbo v. Don-Joy Co., 762 F.2d 969, 973 (Fed. Cir. 1985). In addition, the moving party must be entitled to judgment as a matter of law. In these circumstances summary judgment would be inappropriate.

First, CalMed has established a reasonable likelihood of success on the merits of its case regarding infringement by EMPI's hard plastic collar. Thus, EMPI is not entitled to judgment as a matter of law on that claim of infringement. Second, genuine issues of material fact regarding the foam collar remain to be explored at trial. Therefore, EMPI is not entitled to summary judgment on that claim of infringement.

IV. CONCLUSION AND ORDER

Accordingly, CalMed's motion for preliminary injunctive relief is granted as to the hard plastic collar (Pl.'s Ex. 5) and denied as to the foam collar (Pl.'s Ex. 10). EMPI's motion for summary judgment is denied on both claims of infringement asserted by plaintiff CalMed.

It is so ordered:



Ronald R. Lagueux
United States District Judge
June 24, 1992